



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2012-D-1002]

Questions and Answers Regarding Food Facility Registration (Seventh Edition); Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." The revised draft guidance supersedes the version of the food facility registration draft guidance that we announced on November 8, 2016. When finalized, this guidance is intended to provide updated information relating to the food facility registration requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the revised draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the revised draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-1002 for the revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Courtney Buchanan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2487.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." The revised draft guidance supersedes the version of the food facility registration draft guidance that we announced on November 8, 2016 (81 FR 78526). We are issuing the revised draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public.

You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

On October 10, 2003, FDA issued an interim final rule (68 FR 58893) to implement amendments to the FD&C Act made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. Section 102 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act to, among other things, require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to submit additional registration information to FDA. Section 102 of FSMA also directed FDA to amend the definition of "retail food establishment" in 21 CFR 1.227. On July 14, 2016, FDA issued a final rule (Registration Final Rule) to amend and update FDA's registration regulation and implement the FSMA revisions (81 FR 45912; July 14, 2016).

This revised draft guidance was developed to answer frequently asked questions relating to the registration requirements of section 415 of the FD&C Act. The first edition of the guidance was issued as Level 2 guidance consistent with our good guidance practices regulation (21 CFR 10.115) and was made available on FDA's Web site on December 4, 2003. The second, third, fourth, and fifth editions of the guidance were issued as Level 1 guidance documents under 21 CFR 10.115 and were made available on FDA's Web site on January 12, 2004; February 17, 2004; August 6, 2004; and December 17, 2012, respectively. The sixth edition of the guidance was issued as Level 1 guidance and included one additional question and answer relating to a

proposed amendment to the "farm" definition in 21 CFR 1.227 (see 79 FR 58523; September 29, 2014). Since publication of the sixth edition of the guidance, we have issued the Registration Final Rule. In addition, we have issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule (80 FR 55908; September 17, 2015) that, among other things, revised the definition of "farm" in 21 CFR 1.227. We have also issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule (80 FR 56169; September 17, 2015). We are issuing a seventh edition of the guidance to add information relating to the Registration Final Rule and the revised "farm" definition, as well as to address questions received from stakeholders since publication of the sixth edition.

This edition of the guidance also revises information in existing questions and answers, removes some questions and answers, and makes editorial changes (e.g., we reorganized existing questions and answers) to improve clarity. For the revised questions and answers, we are not adding a date indicating when the questions and answers were revised. As in the previous editions, the following indicators are used to help users identify revisions: (1) The guidance is identified as a revision of a previously issued document; (2) the revision date appears on the cover of the guidance; (3) the edition number of the guidance is included in its title; and (4) questions and answers that have been added since the sixth edition are identified as such in the body of the guidance.

On November 8, 2016, we announced the availability of a draft guidance entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry." The draft guidance contained 15 sections of a multi-section guidance intended to provide updated information relating to the food facility registration requirements of section 415

of the FD&C Act. We reserved two sections in the draft guidance and stated that we would issue a revised draft guidance at a later date that would include those reserved sections.

This revised draft guidance supersedes the food facility registration draft guidance that we issued in November 2016. In the revised draft guidance, we are including the 15 sections that were announced in the Federal Register on November 8, 2016, as well as including the two sections we reserved, "Who is Exempt from Registration?" and "Definitions," from the draft guidance. The revised draft guidance also includes an additional question and answer related to mobile facilities in the section entitled "What Information is Required in the Registration?"

We are inviting comments on the revised draft guidance as a whole. As FDA considers the development of the final guidance, we will review comments received on the revised draft guidance, as well as the comments received on the food facility registration draft guidance we announced on November 8, 2016.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 1.230 through 1.235 and 21 CFR 1.245 have been approved under OMB control number 0910-0502.

Dated: December 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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